## REMARKS UNDER 37 CFR § 1.111

### Formal Matters

Claims 2, 3, 7-9, 11, 12, 14, 17-36 and are pending after entry of the amendments set forth herein.

Claims 1-22 were examined. Claims 1-22 were rejected. No claims were allowed.

Please cancel claims 1, 4-6, 10, 13, 15, and 16. Add new claims 23-36 as provided above.

Please replace claims 2,7,8, and 11 with the clean version provided above.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

No new matter has been added.

As requested by the office action, applicant confirms that amended claims 33-40 have been renumbered as claims 15-22.

### Double Patenting Rejection

The rejection of claims 15-22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,727,969 to Bennetti et al. ("Bennetti") in view of U.S. Patent No. 5,782,746 to Wright ("Wright") is respectfully traversed. Claims 15 and 16 have been canceled, rendering their rejection moot. However, with respect to claims 17-22, Bennetti does not claim a dome shaped housing or a device consisting of a pair of interlinked shafts holding suction port assemblies, therefore the present invention is clearly distinguishable from the device claimed in Bennetti. For this reason, the present rejection towards the described invention should be withdrawn.

The rejection of claim 16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of Bennetti in view of the Roux et al. article entitled "New Helper Instrument in Cardiac Surgery," is also respectfully traversed. Claim 16 has been canceled, thus rendering the rejection moot.

**Rejection under 35 U.S.C. § 102 (e)**

The rejection of claims 1-22 under 35 U.S.C. § 102 (e) as being anticipated by Wright are respectfully traversed. Wright describes an annular or U-shaped device for the immobilization of the heart surface by means of negative pressure. Wright, however, does not teach or suggest a dome shaped device. Furthermore, applicant respectfully disagrees with the statement on page 3 of the outstanding office action stating that the described device under Wright is dome-shaped. Wright makes clear that the described device is annular with inner and outer rings that form seals with the heart surface, whereby partial vacuum is applied to the area between the seals. Newly submitted claim 23 substantially incorporates the vocabulary of claims 1 and 6 as originally presented. Claim 23 as now presented contains only the limitations of originally filed claims 1 and 6. Thereby this amendment does not narrow the scope of claim 6 (now claim 23) within the meaning of *Festo*. Claim 2, 7, 8 have been amended to depend from new claim 23 and are also allowable, for at least the same reasons.

The rejection of claims 1-14 and 16 under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent 5,927,284 to Borst et al. ("Borst") is respectfully traversed. The device of Borst consists of a suction pad attached to a semi-rigid arm, whereby two devices are placed on the heart surface in parallel to each other. Furthermore, the semi rigid arms of the two devices are not attached or closely associated to one another in any form. This is clearly distinguishable from the present invention, which makes clear that the rigid arms holding the suction port assemblies are associated to one another by means of a pivot link at an intermediate point in the shafts. It is respectfully submitted that Borst clearly fails to disclose or suggest a dome-shaped housing, or a pair of shafts interlinked by a pivot. Claims 1 and 10 have been cancelled and new claims 23 and 24 have been submitted which substantially combine claims 1 and 6, and 10 and 13, respectively. Thereby this amendment does not narrow the scope of claim 6z (now claim 23) or claim 10 (now claim 24) within the meaning of *Festo*.

**Rejection Under 35 U.S.C § 103 (a)**

The rejection of claims 15 and 17-22 under 35 U.S.C. § 103 (a) as unpatentable over Borst in view of Wright is respectfully traversed. As previously stated, Wright does not disclose or suggest a dome shaped device. Wright describes an annular apparatus that rests upon the heart surface and stabilizes the area of the heart at the center of the annulus for surgical procedures. Furthermore, the

device disclosed in Wright does not possess suction ports, rather, the device consists of a relatively flat annular element that rests upon the heart surface, whereby the inner and outer edges form a seal with the heart surface, and subsequently vacuum pressure is applied to the entire area in between the two concentric edges of the annular device. Alternatively, Borst describes a paddle-shaped suction device that is attached to a semi-rigid arm. There is no suggestion in either of the cited references that would lead one of ordinary skill in the art to replace the paddle of Borst with a dome-shaped housing, even if Wright did disclose a dome-shaped housing, which it does not. For this reason, the present rejection towards the described invention should be withdrawn.

Applicant notes that in rewriting the claims in this manner, that the claims have not been narrowed from their previous scope since all the limitations now expressly set forth were previously implicit to the claims before. The cited references do not disclose or suggest either a dome shaped housing or a pair of shafts interlinked by a pivot. Therefore, new claims 23 and 24 submitted herewith are in condition for allowance.

Newly presented claims 25-28 recite method steps for attaching the device of the present invention to the surface of the heart which are not disclosed or taught by the references of record.

New claims 29-31 recite a device having an annular housing having a plurality of suctions ports in the bottom surface thereof, which is also neither neither disclosed nor taught by the art of record.

New claims 32-34 recite a method of using an instrument having first and second shaft attached to first and second suction ports and being interlocked by a pivot, which is neither taught nor disclosed by the prior art of record.

New claims 35-36 depend from claim 8 and are allowable for at least the same reasons, provided above, that claim 8 is allowable.

**Conclusion**

In view of the above amendments and remarks, applicant respectfully request reconsideration of the outstanding office action.

Applicant submits that all of the claims are in condition for allowance, which such action is earnestly solicited. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number GUID-003DIV2.

Respectfully submitted,
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## VERSION WITH MARKINGS TO SHOW CHANGES MADE

**In the Specification**

The paragraph beginning on page 1 after the title, which was newly added by the Preliminary Amendment, was amended above as follows:

(Amended) This is a divisional of [copending] application Serial No. 08/870,687 filed on June 6, 1997, now U.S. Patent No. 6,032,672, which is a divisional of application Serial No. 08/603,328 filed on February 20, 1996 and issued as United States Patent No. 5,727,569 [issued] on March 17, 1998. The priority of [this application is] these applications are expressly claimed and [disclosure is] these applications are hereby incorporated by reference in their entireties.

The paragraph beginning on page 5, line 1 was amended above as follows:

(Amended) and is applied at several points over the surface of the heart proximate to or surrounding the portion of the heart whose position is desired to be fixed during the procedure. The instruments feature several suction ports which are brought into contact with the heart, followed by the application of a negative pressure through the instrument, to fix the position of the tissue based on the placement of the instrument. The instruments may also contain a sealed, airtight [,] pressure conducting chamber for operably [connected] connecting to a pressure inlet for communicating the negative pressure to the suction [parts] ports. Alternatively, each suction port may have a dedicated vacuum line attached thereto.

The paragraph beginning on page 9, line 2 was amended above as follows:

(Amended) Referring to Figure 2, a dome-shaped or semi-spherical embodiment of the invention has a plurality of suction ports 2 spaced about the periphery of the bottom surface 6 of the dome portion 8 such that the entire instrument is fixed to the cardiac tissue at the point of each of the several suction ports 2. As with the above embodiment, it is preferred that each suction port 2 be

pneumatically connected via an air-tight pressure conducting chamber 4. The base of the instrument is comprised of a substantially flat bottom surface 6 wherein the opening of each of the suction ports 2 is flush at the bottom surface 6. The bottom surface 6 is preferably substantially flat because the bottom surface 6 will engage the surface of the heart when the negative pressure is imposed. Alternatively, depending on the size of the instrument and the location of placement on the surface of the heart, the bottom surface 6 may be contoured so that the suction ports 2 may engage a curved surface of the heart. The bottom surface 6 may also have a separate contact layer 7 to cushion the contact between the instrument and the heart tissue and to facilitate forming a tight seal when the negative pressure is imposed. The contact layer may cover substantially the entire bottom surface 6 proximate to the openings of the suction ports 2. If the material surrounds the openings of the suction ports, it is preferable that the material not be air permeable to prevent the negative pressure from passing through the contact layer 7. Also, the contact layer 7 may be attached at the periphery of the bottom surface 6. The available materials for the contact layer 7 include the well-known and commercially available medical plastics such as TEFLON®, [teflon, silicon] silicone, and others

The paragraph beginning on page 12, line 6 was amended above as follows:

(Amended) Referring to Figure 4, Figure 4 shows an embodiment of the invention in use in a coronary artery bypass graft (CABG) procedure where an anastomosis is formed between the internal mammary artery IMA 13 and the left anterior descending artery LAD 14 and which is held open by vessel [refractors] retractors 16a and 16b. One end of the anastomosis is sewn to the LAD 14 by sutures 17 being manipulated by instrument 10. A vacuum line 3 is attached to inlet 5, to introduce a negative pressure to the pressure conducting chamber 4. An instrument 10, which in this example is manipulating suture 17 for sewing the anastomosis at the LAD 14, is introduced via instrument port 9a located in the housing 1 of the apparatus. An instrument port 9a has a shaft 18 disposed within the instrument port 9a to facilitate positioning the instrument 10 relative to both the housing 1 and to the surgical site. The shaft 18 traverses all or a portion of the instrument port 9a and may be flexible such that the shaft 10 can be oriented in a fashion to direct the instrument 10 to the desired point within the surgical field. The shaft 18 may also be incorporated into a pivot 24 of any of several configurations including a ball 25 and socket 26 joint having a passage 27 running axially through the ball 25 wherein the shaft 18 is contained in the passage 27 such that the ball 25 is rotated within the

The paragraph beginning on page 14, line 1 was amended above as follows:

(Amended) comprised of the block 23, in which the suction ports 2 are contained, and a receiving means 29 located at the terminal (lower) end of the shaft 21 which is shaped to receive the block 23 and to [pen-nit] permit introduction of the negative pressure from vacuum line 3 to the suction ports 2 contained within the block. The negative pressure is preferably, imposed by one or more vacuum lines 3 which may be run parallel to the shaft 21 before terminating in the block 23 containing the suction ports 2 or at any convenient point in the suction port assembly 22. In a preferred embodiment, the blocks 23 are substantially rectangular structures wherein the [parts] ports 2 are placed in an array as described above.

**In the Claims**

Claims 2, 7, 8, and 11 were amended above as follows:

2. (Amended) The device of claim [1] 23 further comprising a means for introducing a negative pressure located in the interior of the housing.

7. (Amended) The device of claim [6] 2 wherein the means for introducing a negative pressure is comprised of an inlet and a pressure conducting chamber connected to each suction port.

8. (Amended) The device of claim [6] 23 further comprising at least one instrument port located in the dome-shaped portion of the housing.

11. (Amended) The device of claim [10] 24 wherein the opening of the plurality of suction ports are disposed in the bottom surface of the block.